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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,215	04/07/2004	Eric J. Benjamin	AM101252	7245

38791 7590 06/01/2006

WOODCOCK WASHBURN LLP
ONE LIBERTY PLACE - 46TH FLOOR
PHILADELPHIA, PA 19103

EXAMINER	
COLEMAN, BRENDA LIBBY	
ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/820,215	BENJAMIN ET AL.	
	Examiner	Art Unit	
	Brenda L. Coleman	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/04 & 8/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-56 are pending in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The scope of the composition claims are not adequately enabled solely based on the inhibition of the excitatory amino acid receptors provided in the specification.

In evaluating the enablement question, several factors are to be considered. In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988); Ex parte Forman, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

The nature of the instant invention has claims, which embrace substituted 8,9-dioxo-2,6-diazabicyclo[5.2.0]non-1(7)-en-2-yl compounds.

HOW TO USE: Claims 1-9 and 26-41 are to a pharmaceutical composition for the treatment or prevention of any and all diseases and/or conditions associated with excitatory amino acid receptor activity. Any evidence presented must be commensurate in scope with the claims and must clearly demonstrate the effectiveness of the claimed compounds. The scope of claims 10-23 and 42-56 includes diseases and/or conditions not even known at this time, which may be associated with excitatory amino acid inhibiting activity. While the treatment of cerebral ischemia has been linked with NMDA the art does not recognize use of such inhibitors as broad based drugs for treating all disorders instantly embraced.

It is difficult to treat many of the disorders claimed herein. Instant claim language embraces disorders not only for treatment but the **prevention**, which is not remotely enabled. It is presumed in the prevention of the diseases and/or disorders claimed herein there is a way of identifying those people who may develop a tolerance to opiate analgesia, etc. There is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the disorders claimed herein.

Where the utility is unusual or difficult to treat or speculative, the examiner has authority to require evidence that tests relied upon are reasonably predictive of in vivo efficacy by those skilled in the art. See *In re Ruskin*, 148 USPQ 221; *Ex parte Jovanovics*, 211 USPQ 907; MPEP 2164.05(a).

Patent Protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Tossing out the mere germ of an idea does not constitute enabling disclosure. *Genentech Inc. v. Novo Nordisk* 42 USPQ2d 1001.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 25, 26, 33, 54 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a) A pain relieving agent in claims 25 and 54 is a relative terms, which renders the claim indefinite. The specific term of claims 25 and 54 "pain relieving agent" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The nature of the composition consisting of the compounds of formula I and an additional active ingredient, which is a pain relieving agent.

b) Claim 26 is vague and indefinite in that it is a duplicate of claim 1.

c) Claim 33 recites the limitation "2,2-dimethyl-propionic acid" in the species labeled c. There is insufficient antecedent basis for this limitation in the claim.

d) Claim 56 recites the limitation "2,2-dimethyl-propionic acid" in the species labeled c. There is insufficient antecedent basis for this limitation in the claim.

Claim Rej ctions - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-26 are rejected under 35 U.S.C. 102(a) as being anticipated by CHILDERS et al., Drugs of the Future. Childers teaches the composition and method of use of the compounds of formula (I) where A is $-CH_2CH_2-$ and R_1, R_2 and R_3 is H as shown on page 633.

4. Claims 1-26 are rejected under 35 U.S.C. 102(b) as being anticipated by BAUDY et al., Journal of Medicinal Chemistry. Baudy teaches the composition and method of use of the compounds of formula (I) where A is $-CH_2CH_2-$ and R_1, R_2 and R_3 is H as shown in figure 4.

5. Claims 1-26 are rejected under 35 U.S.C. 102(b) as being anticipated by LIN et al., EP 0 778 023. Lin teaches the composition and method of use of the compounds of formula (I) where A is $-CH_2CH_2-$ and R_1, R_2 and R_3 is H. See page 3, lines 9-10.

6. Claims 1-26 are rejected under 35 U.S.C. 102(b) as being anticipated by KINNEY et al., Journal of Medicinal Chemistry. Kinney teaches the composition and

method of use of the compounds of formula (I) where A is $-CH_2CH_2-$ and R_1, R_2 and R_3 is H as shown by example 15.

7. Claims 1-26 are rejected under 35 U.S.C. 102(b) as being anticipated by KINNEY et al., U.S. Patent No. 5,240,946 and 5,168,103. Kinney teaches the composition and method of use of the compounds of formula (I) where A is $-CH_2CH_2-$ and R_1, R_2 and R_3 is H as shown by example 8.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-9 and 26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-29 of copending Application No. 10/969,715. Although the conflicting claims are not identical,

they are not patentably distinct from each other because the composition of formula (I) of the instant invention where R_1, R_2 and R_3 is H is embraced by the compositions of 10/969,715.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 27-55 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-28 of copending Application No. 10/820,216. Although the conflicting claims are not identical, they are not patentably distinct from each other because the composition of formula (I) of the instant invention where R_2 or R_3 is $-C(R_4)(R_5)-O-C(=O)-R_6$, $-C(R_4)(R_5)-O-C(=O)-O-R_6$ or $-C(R_4)(R_5)-O-C(=O)-N(R_7)-R_6$ is embraced by the compositions of 10/820,216.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 27-56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-95 and 104-108 of copending Application No. 10/961,871. Although the conflicting claims are not identical, they are not patentably distinct from each other because the composition of formula (I) of the instant invention where R_2 or R_3 is $-C(R_4)(R_5)-O-C(=O)-R_6$, $-C(R_4)(R_5)-O-C(=O)-O-R_6$ or $-C(R_4)(R_5)-O-C(=O)-N(R_7)-R_6$ is embraced by the compositions of 10/961,871.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 21-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 37-53 and 57-73 of copending Application No. 10/267,159. Although the conflicting claims are not identical, they are not patentably distinct from each other because the composition of formula (I) of the instant invention where R_1, R_2 and R_3 is H is embraced by the compositions of 10/267,159.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brenda L. Coleman
Primary Examiner Art Unit 1624
May 30, 2006